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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/646,539	08/22/2003	Jay Douglas Audett	ARC3254R1/A5033	9721
27777	7590	08/15/2006		EXAMINER
PHILIP S. JOHNSON JOHNSON & JOHNSON ONE JOHNSON & JOHNSON PLAZA NEW BRUNSWICK, NJ 08933-7003			CHANG, VICTOR S	
			ART UNIT	PAPER NUMBER
			1771	

DATE MAILED: 08/15/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	10/646,539	AUDETT, JAY DOUGLAS
	<b>Examiner</b> Victor S. Chang	<b>Art Unit</b> 1771

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 28 June 2006.
- 2a) This action is FINAL.                  2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 14-16 and 18-31 is/are pending in the application.
- 4a) Of the above claim(s) 24 is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 14-16, 18-23 and 25-31 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:
1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____. | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
|   | 6) <input type="checkbox"/> Other: _____.                                   |

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Applicant's election with traverse of species in claim 25 in the reply filed on 6/28/2006 is acknowledged. The traversal is on the ground that the species of claim 24 and claim 25 can be efficiently searched without undue burden. This is not found persuasive because the general test as to when claims are restrictable to different species is the fact that one claim recites limitations which under the disclosure are found in a first species but not in a second, while a second claim recites limitations disclosed only for the second species and not the first. See MPEP 806.04(f). For example, coated paper product is found in claim 24, but not in claim 25. Claims 14-16, 18-23 and 25-31 are active.

The requirement is still deemed proper and is therefore made FINAL.

### ***Claim Objections***

2. Claim 20 is objected to because of the following informalities:

At line 2, the term "multilaminate" has been misspelled as "mulilaminate". Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 14-16, 18-23 and 25-31 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential structural cooperative relationship of elements, such omission amounting to a gap between the necessary structural connections. See MPEP § 2172.01. The omitted structural cooperative relationship is the shape (is it a layer?) and placement of the secondary drug-containing reservoir within the multilaminate tie layer. For the present Office action, it is presumed that the reservoir is a layer overlay a base layer, as shown in Fig. 2.

Clarification is requested.

***Claim Rejections - 35 USC § 102***

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 14, 15, 19 and 25 are rejected under 35 U.S.C. 102(b) as being anticipated by Burkoth et al. (US 5785991).

Burkoth's invention relates to a transdermal drug delivery device. In Fig. 2, Burkoth shows an embodiment comprising a multi-laminate drug formulation/enhancer reservoir 11 having three layers 12, 13 and 14 in sequence (multilaminate tie layer). An optional rate-controlling membrane (base layer) for controlling the release rate of the enhancer from zone 12 to the skin 17 may be utilized [col. 7, lines 43-59]. The embodiment of Fig. 2 can be fully

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enclosed in a permeable or microporous skin-contacting membrane (outer layer) [col. 8, lines 14-19].

For claims 14, 15 and 25, the examiner takes Official notice that a microporous membrane, e.g., a microporous polyethylene membrane, is inherently embossable, writable and breathable. Burkoth discloses all the features as claimed.

For claim 19, Burkoth teaches that suitable materials for rate controlling membrane (base layer) include polyethylene, polyvinyl acetate and ethylene vinyl acetate copolymers [col. 7, lines 60-67].

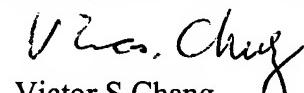
***Conclusion***

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Victor S. Chang whose telephone number is 571-272-1474. The examiner can normally be reached on 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terrel H. Morris can be reached on 571-272-1478. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Victor S Chang  
Examiner  
Art Unit 1771

8/10/2006